REMARKS

The present communication responds to the office action of February 8, 2007 in which the examiner rejected claims 2-5, 8, 10, 11, 13, 14, 16, 19-21, 33, and 37. Claims 2, 4, and 16 have been cancelled. Claims 3, 8, 10, 11, and 13 have been amended. New claims 53-56 have been added. Support for the amendments to claim 8 is provided, for example, at page 10 of the specification. Support for the amendments to claim 3 is provided, for example, at page 5. Support for the amendments to claims 10, 11, and 13 is inherent in each of the claims. Support for new claims 53 and 55 can be found, for example, at pages 2 and 8, and support for new claims 54 and 56 can be found, for example, at page 8. No new matter has been added by the amendments or new claims.

The claim rejections are traversed in view of the amendments above and for at least the reasons articulated herein below. Entry, reconsideration, and withdrawal of the rejections are therefore requested.

Rejection under 35 U.S.C. § 103

Claims 2-5, 8, 10, 11, 13, 14, 16, 19-21, 33 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 4,306,563 ("Iwatschenko") in view of U.S. Patent 4,835,248 ("Bader").

Independent claim 8 has been amended and is directed toward a cannula which increases in pliability during use. The cannula comprises a first polymer material with a hardness that is thermally susceptible. The cannula also comprises a second material with a second hardness. During use, the hardness of the first material decreases due to its thermal susceptibility.

Iwatschenko discloses a catheter made of a high-molecular material. (Iwatschenko, Abstract). Iwatschenko further discloses an external stiffening coating which is soluble in body fluids. (*Id*). However, Iwatschenko says nothing of a material with a hardness that is thermally susceptible and further where the thermal susceptibility causes a decrease in the hardness of the material during use. Bader fails to remedy the deficiency of Iwatschenko because it is directed toward a biologically degradable polyamide for depot preparations of an active compound having controlled release of the active compound. (Bader, col. 3, ll. 9-11.) Bader, like

Iwatschenko, fails to disclose anything relating to a material with a thermally susceptible hardness wherein the thermal susceptibility causes a decrease in the hardness of the material during use.

Neither Iwatschenko nor Bader, alone or in combination, teach, suggest, or provide any motivation to combine their teachings to reach the subject matter of claim 8 and it is, thus, not obvious over Iwatschenko in view of Bader. All of claims, 3, 5, 10, 11, 13, 14, 19-21, 53, and 54 depend directly or indirectly from claim 8, recite additional limitations, and are patentable for the same reasons as claim 8. Moreover, claim 53 recites a skin, or septum, piercing tip. This is distinguishable from Iwatschenko which is directed to a catheter and not a cannula. The stiffening coating in Iwatschenko is intended to assist insertion of a catheter into an orifice and through a passage way, but not to provide for piercing penetration. This distinction is further exploited in claim 54 which recites a hardness of the first material equal to that of a steel needle which would allow for the cannula to penetrate a membrane.

Claim 33 is directed toward a cannula that increases in pliability during use, wherein the cannula comprises a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water absorption, and a material having a second hardness. Iwatschenko discloses an external stiffening coating which is soluble in body fluids. (Iwatschenko, Abstract). However, Iwatschenko says nothing of a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water-absorption. Bader does not remedy the deficiency of Iwatschenko simply by disclosing a biologically degradable polyamide for depot preparations. (Bader, col. 3, ll. 9-11.) Bader, like Iwatschenko, fails to disclose a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water-absorption. This is because dissolving in water and leaving behind an underlying material is different that absorbing water which leaves the material intact and only makes it more pliable.

Legitimate concerns are raised when materials dissolve within the body. These concerns relate to biocompatibility, blockage, etc. Where a material merely absorbs water and becomes more pliable, the concerns relating to a dissolved material's effect on the body can be avoided. Neither Iwatschenko nor Bader, alone or in combination, teach, suggest, or provide any

motivation for the success of including a water-absorbing material based on a polyamide of a first variable hardness that decreases in hardness upon water absorption. Thus, claim 33 is not obvious over Iwatschenko in view of Bader. Claims 37, 55, and 56 depend from claim 33 and recite additional limitations. Thus, these dependent claims are patentable for at least the same reasons as claim 33. Moreover, as discussed with respect to claims 53 and 54, a cannula is used to penetrate a membrane whereas a catheter, as in Iwatschenko, is inserted into an orifice and through a passage way. The additional recitations of claims 55 and 56 are thus further distinguishable from Iwatschenko.

Entry of the new claims, and to reconsideration and withdrawal of the obviousness rejections are requested.

CONCLUSION

This response is being submitted on or before August 8, 2007, with the required fee of $1,020.00 for a three-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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Date: August 7, 2007

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